

JUL - 9 2001

**Attachment 1F
510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K010841

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121
Phone: 858-535-2030
Fax: 858-535-2035

Date:

18 March 2001

Contact Person:

Robert Hudak

Product Name:

ACON[®] COC One Step Cocaine Test Strip
ACON[®] COC One Step Cocaine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of the cocaine metabolite, benzoylecgonine, in urine specimens.

Device Classification:

The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are similar to other FDA-cleared devices for the qualitative detection of benzoylecgonine in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3250). Cocaine and cocaine metabolite test systems have been classified as Class II devices, moderate complexity.

Classification Name:

Cocaine and cocaine metabolite test system



Intended Use:

The ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of the cocaine metabolite, benzoylecgonine, in human urine at a cut-off concentration of 300 ng/mL

Description:

The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of the cocaine metabolite, benzoylecgonine, in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a monoclonal antibody to selectively detect elevated levels of the cocaine metabolite, benzoylecgonine, in urine at a cut-off concentration of 300 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug negative urine specimen will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Predicate Device:

LifeSign Status DS™ COC One-Step Cocaine Test

510(k) Number K945609

Distributor:

LifeSign

71 Veronica Avenue

Somerset, New Jersey 08873

Comparison to a Predicate Device:

A summary comparison of the features of the ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device and the LifeSign Status DS COC One-Step Cocaine Test is shown below.

- Both tests are assays intended for the qualitative detection of the cocaine metabolite, benzoylecgonine, in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for rapid detection of benzoylecgonine with a visual, qualitative end results.
- Both tests utilize the same basic immunoassay principles that rely on antigen / antibody interactions to indicate a positive or negative result.
- Both tests have a benzoylecgonine cut-off concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 specimens. This evaluation compared the results of the ACON[®] COC One Step Cocaine Test Strip and the ACON[®] COC One Step Cocaine Test Device and the LifeSign Status DS[™] COC One-Step Cocaine Test to the customary Gas Chromatography/Mass Spectrometry analysis technique. The data from this study yielded the following results:

ACON COC One Step Cocaine Test Strip compared to the LifeSign Status DS COC One-Step Cocaine Test:

Positive Agreement: 136 / 143 = 95%
Negative Agreement: 157 / 157 = >99%
Overall Agreement: 293 / 300 = 98%

ACON COC One Step Cocaine Test Device compared to the LifeSign Status DS COC One-Step Cocaine Test:

Positive Agreement: 136 / 143 = 95%
Negative Agreement: 157 / 157 = >99%
Overall Agreement: 293 / 300 = 98%

ACON COC One Step Cocaine Test Strip compared to GC/MS:

Positive Agreement: 119 / 124 = 96% (91 - 99%) *
Negative Agreement: 159 / 176 = 90% (85 - 94%) *
Overall Agreement: 278 / 300 = 93% (89 - 95%) *

ACON COC One Step Cocaine Test Device compared to GC/MS

Positive Agreement: 119 / 124 = 96% (91 - 99%) *
Negative Agreement: 159 / 176 = 90% (85 - 94%) *
Overall Agreement: 278 / 300 = 93% (89 - 95%) *

*** Denotes 95% confidence intervals**

Sensitivity

A drug-free urine pool was spiked with benzoylecgonine to the following concentrations: 0, 150, 225, 300, 375 and 450 ng/mL. Each concentration level was tested in replicates of thirty (30) with both the ACON[®] COC One Step Cocaine Test Strip and ACON[®] COC One Step Cocaine Test Device. The data indicate 100% accuracy at 50% above and 50% below the cut-off concentration of 300 ng/mL.

Analytical sensitivity of the ACON Cocaine Test Strip

Benzoylecgonine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
150 ng/mL	50%	30	30	0
225 ng/mL	75%	30	30	0
300 ng/mL	Cut-off	30	4	26
375 ng/mL	125%	30	0	30
450 ng/mL	150%	30	0	30

Analytical sensitivity of the ACON Cocaine Test Device

Benzoylecgonine Concentration (ng/mL)	% Cut-off	n	Visual Result	
			Negative	Positive
Negative urine	0	30	30	0
150 ng/mL	50%	30	30	0
225 ng/mL	75%	30	30	0
300 ng/mL	Cut-off	30	9	21
375 ng/mL	125%	30	7	23
450 ng/mL	150%	30	0	30

Specificity

Specificity studies were conducted by individually spiking various cocaine related compounds and metabolites into drug-free urine. These samples were further diluted sequentially to different concentrations and were evaluated in triplicate until the lowest concentration that yielded a positive result was identified. The following compounds gave positive results at the respective concentrations. The % Cross Reactivity was determined from these concentrations.

Compounds	Concentration (ng/mL)	% Cross Reactivity
Benzoylecgonine	300	100
Cocaine hydrochloride	780	38
Cocaethylene	12,500	2
Ecgonine hydrochloride	32,000	1

Interfering Substances

No interference was observed in our studies when using negative or positive specimens (450 ng/mL of benzoylecgonine) containing the following substances at a final concentration of 100 ug/mL:

Acetaminophen	Diazepam	Methoxyphenamine	L – Phenylephrine
Acetaphenetidine	Diclofenac	(+) 3,4-Methylenedioxy	B – Phenylethylamine
N-Acetylprocainamide	Diffunisal	Amphetamine	Phenylpropanolamine
Acetylsalicylic acid	Digoxin	(+) 3,4-Methylenedioxy	Prednisolone
Aminopyrine	Diphenhydramine	Methamphetamine	Prednisone
Amitriptyline	Doxylamine	Morphine -3 -B -D	Procaine
Amobarbital	Ecgonine methylester	Glucuronide	Quinidine
Ampicillin	(-)Y-Ephedrine	Morphine sulfate	Quinine
L-Ascorbic acid	Erythromycin	Nalidixic Acid	Ranitidine
Amoxicillin	B-Estadiol	Naloxone	Salicylic Acid
D-L-Amphetamine	Estrone-3-Sulfate	Naltrexone	Secobarbital
Apomorphine	Ethyl-p-aminobenzoate	Naproxen	Serotonin
Aspartame	Fenoprofen	Niaciamide	Sulfamethazine
Atropine	Furosemide	Nifedipine	Prednisolone
Benzilic Acid	Gentisic Acid	Norcodeine	Sulindac
Benzoic Acid	Hydralazine	Norothindrone	Temazepam
Benzphetamine	Hydrochlorothiazide	D-Norpropoxyphene	Tetracycline
Bilirubin	Hydrocodone	Noscapine	Tetrahydrocortisone-3
Brompheniramine	Hydrocortisone	D,L Octopamine	Acetate
Caffeine	O-Hydroxyhippuric Acid	Oxalic Acid	Tetrahydrocortisone-3-B-
Cannabidiol	P-Hydroxymeth	Oxazepam	D Glucuronide
Cannabinol	3-Hydroxytyramine	Oxolinic Acid	Tetrahydrozoline
Chloralhydrate	Ibuprofen	Oxycodone	Thebaine
Chloramphenicol	Imipramine	Oxymetazoline	Thiamine
Chlordiazepoxide	Iproniazid	Promazine	Thioridazine
Chlorothiazide	(-)Isoproterenol	Promethazine	D,L – Tyroxine
(±)Chlorpheniramine	Isosuprine	D,L - Propanolol	Tolbutamine
Chlompromazine	Ketamine	D- Propoxyphene	Triamterene
Chloroquine	Ketoprofen	D- Pseudoephedrine	Trifluoperazine
Cholesterol	Labetanol	Papaverine	Trimethoprim
Clomipramine	Levorphanol	Penicillin – G	Trimipramine
Clonidine	Loperamide	Pentobarbital	Tryptamine
Codeine	Hemoglobin	Perphenazine	D,L – Tryptophan
Cortisone	Maprotiline	Phencyclidine	Tyramine
(-) Cotinine	Meprobamate	Phenelzine	Uric Acid
Creatinine	Meperidine	Phenolbarbital	Verapamil
Deoxycorticosterone	Methadone	Phentermine	Zomepirac
Dextromethorphan			

Intra and inter-assay variability

Studies to evaluate intra- and inter-assay variability demonstrated that the test yielded the expected results >99% of the time.

Lot-to-Lot Variability

Studies to evaluate the manufacturability and consistency of the product on a lot-to-lot basis have shown this test to be highly reproducible.

Conclusion

These studies demonstrate the substantial equivalency of the ACON® COC One Step Cocaine Test Strip and ACON® COC One Step Cocaine Test Device to the LifeSign Status DS™ COC One-Step Cocaine Test, which is already marketed. They further demonstrate the suitability of this product for professional and point-of-care use, in addition to demonstrating their safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert Hudak
Vice President, Research and Development
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

JUL - 9 2001

Re: K010841
Trade Name: ACON® COC One Step Cocaine Test Strip and ACON® COC One Step
Cocaine Test Device
Regulation Number: 21 CFR § 862.3250
Regulatory Class: II
Product Code: DIO
Dated: May 25, 2001
Received: June 18, 2001

Dear Mr. Hudak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

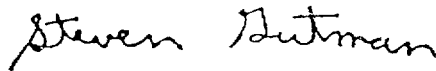
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number:

K010841

Device Name:

ACON® COC One Step Cocaine Test Strip
ACON® COC One Step Cocaine Test Device

Indications for Use:

The ACON COC One Step Cocaine Test Strip and ACON COC One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of the cocaine metabolite, benzoylecgonine, in human urine at a cut-off concentration of 300 ng/mL. These tests are for use by Healthcare Professionals only.

Arlene Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010841

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

☒

Or

Over-The-Counter Use

(Per 21 CFR 801.109)